

Instructions for Crosswalk Forms

Please make an entry for each patient who is referred to you for the study or that you have approached for the study.

Use black ballpoint pen only. Do not use white-out or obliterate mistakes in any way, just put a single line through the error, then initial and date the correction.

This is a two page form, so make sure that you complete both pages for each patient.

Please do not put any patient identifying data such as initials or hospital ID numbers on Crosswalk 1. This will enable you to submit crosswalk 1 to Ann Arbor without compromising patient confidentiality.

Line # - The line numbers shown as a reference between Crosswalk 1 and Crosswalk 2. The patient on line one of crosswalk 1 will be the same patient on line 1 of crosswalk 2.

Eligible – If the patient is eligible for the study based on the Screening for Eligibility Worksheet, circle Y. If the patient is not eligible, enter the criteria number from the Screening for Eligibility Worksheet which ruled the patient out.

Consent Date – If the patient gives informed consent enter the date in the space provided. If the patient doesn't consent to the study, please make a note as to why the patient didn't consent.

Consent Version – For every patient who gives informed consent, enter the version date from the consent they have signed.

Enrollment ID – Every patient who gives informed consent is to be assigned an enrollment ID. The first digit has been entered into the crosswalk form for you, this digit is your site #. The next three digits are assigned in order as patients are enrolled at your site (for example, the first patient who gives informed consent is 001 – the full enrollment ID will be 10011). The last digit of an enrollment ID will always be 1, so that it can be easily distinguished from a randomization ID.

Baseline Survey Date – Enter the date that the patient completes the visit 1 survey here.

Randomization ID – At visit 2 if the patient is eligible for randomization enter the randomization ID here. The first four digits will be the same as the patient's enrollment ID. The last digit will always be a 2, to distinguish the randomization ID from the enrollment ID. If the patient will not be randomized to the study, enter the reason. If the patient must be put on hold at visit 2, but could still be randomized, leave this section blank until a final decision has been made.

Envelope # - Patients must be randomized in sequence. When the first patient is randomized, use envelope #1 (for the appropriate season) from your site, when the second patient is randomized use envelope #2 (for the appropriate season), etcetera. Never re-assign an envelope once it has been used to randomize a patient, even if the patient is no longer in the study. Document the envelope # that you used here. At the beginning of a new season, begin with envelope #1 (for the new season) and continue with #2, etc.

Group – This comes from the randomization envelope. It will be 1-control, 2-digiwaker, or 3-sportbrain.

Data from Crosswalk 1 should be entered as each patient is either randomized or once it is determined that he will not be randomized.